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BAXTER HEALTHCARE CORPORATION
RENAL DIVISION
1 BAXTER PARKWAY
DF3-3E
DEERFIELD, IL 60015

EXAMINER	
DRODGE, JOSEPH W	

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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Paper No. 16

Application Number: 09/711,240

Filing Date: November 13, 2000

Appellant(s): Connell et al

Robert M. Barrett

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 16, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying that there are no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 30-41 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,898,578	RUBALCABA	2-1990
4,756,706	KERNS ET AL	7-1988
4,370,983	LICHTENSTEIN	2-1983

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (a) and potential U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

Claims 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein patent 4,370,983 in view of Rubalcaba patent 4,898,578 and/or Kerns et al patent 4,756,706 (hereafter "Kerns").

Lichtenstein discloses a computer controlled medical care system that encompasses extracorporeal blood circulation and treatment systems including means for conducting dialysis treatment of the blood in which numerous parameters are monitored, displayed and controlled through the use of central processing units coupled to interactive data entry devices such as keyboards, monitoring units and alphanumeric, CRT or other types of display units (see column 22, lines 23-35; column 28, lines 60-65 and column 32, lines 62-67). These displays communicate adjustments needed for operation of components such as pumps and valves. The disclosed medical care system can include modules for conducting intravenous and drug infusion for patients in addition to hemodialysis, hemofiltration and a plurality of other medical procedures (column 5, line 34-column 6, line 24 and column 31, lines 12-33).

The claims all differ from Lichtenstein in requiring the system to be operably connected to a touch screen operable for displaying information corresponding to a setting of a parameter and operable to display an indicium permitting a user to perform at least one step of a procedure for changing the setting of the parameter (i.e. operable for controlling the parameter). Although Lichtenstein does disclose use of data processing components generally in column 8, lines 1-16 and column 31, lines 12-33, he is silent as to use of touch screens. However, each of Kerns and Rubalcaba teach such interactive units employed with drug infusion, computer controlled medical care systems.

The systems of both teaching references employ a plurality of modules that may be operated selectively or simultaneously. Kerns teaches a touch screen (display 74) as part of control means to control

or set operating parameters of selected modules including pumped or delivery rates, times, volumes to be infused and system pressures (column 1, line 65-column 2, line 6; column 6, lines 30-51; column 8, lines 41-45 and 59-68 and column 11, lines 39-59). Rubalcaba teaches a touch screen as part of control means to control (i.e. adjust settings of) system operations such as pump infusion rates for selected modules (column 5, lines 21-29; column 6, lines 42-48 and column 6, lines 42-58).

At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have modified the Lichtenstein medical care system by supplementing or substituting at least one touch screen unit for or with the disclosed data entry devices and display units, as taught by Rubalcaba and/or Kerns, in order to prevent user confusion and error in entering data and to prevent such errors from occurring during crisis situations, as suggested by Rubalcaba (column 8, lines 35-45) and/or to prevent confusion in entering data when detaching and reattaching components, as suggested by Kerns (column 1, lines 41-59 together with column 5, lines 32-53 and column 6, lines 12-20).

Regarding these motivations, Lichtenstein discloses that different modules must be matched with corresponding support structure of the system in column 6, lines 20-29, and discloses concern with the complexity of programming required to enable appropriate data entry and control and required to match particular modules with particular programs in column 24, lines 30-55; column 31, lines 26-41 and column 31, lines 54-57).

Concerning claims 30, 32, 33, and 37-40, Lichtenstein discusses extracorporeal blood delivery and circulation and operation and control of a blood pump in column 12, lines 15-48.

Concerning claims 31-34 and 40, Lichtenstein discloses delivery and circulation of dialysate from a source and control of rates and pressures of pumping such dialysate in column 13, lines 38-59.

Concerning claim 35, Lichtenstein, Rubalcaba and Kerns all teach monitoring and control of a plurality of parameters which change with time, both predictably and randomly.

Concerning claim 36, see teachings of numerical keypads forming part of the touch screen in Kerns at column 5, lines 56-59 and column 8, lines 41-45 with figures 7 and 8; and see Rubalcaba at column 5, lines 24-27 with figures 5-7.

Concerning claim 41, Lichtenstein discloses control of dialysate concentration in column 14, lines 42-44.

Arguments pertaining to establishing a prima facie case of obviousness under 35 U.S.C. 103 (a)

(11) Response to Argument

It is argued that Lichtenstein does not disclose a touch screen as a user interface or suggest the need for such a touch screen. However, it is submitted that employ of complex, simultaneous medical procedures ; the need to simplify electronic and data processing components employed; and simultaneous control of multiple, interchangeable modules , all problems which would be at least partly addressed by use of a control system encompassing a controlling, interactive touch screen are addressed; see especially column 24, lines 30-55 and column 32, lines 26-62.

(11) Response to Argument

It is argued that neither Kerns or Rubalcaba describe a hemodialysis system or any form of extracorporeal blood-treatment system or combining a touch screen with such type system. However, it is submitted that they do teach combining touch screens with medical treatment systems used in intensive care, employing multiple, interchangeable modules capable of simultaneously being operated, with such systems

including drug infusion equipment. Thus Kerns and Rubalcaba teach combining of a touch screen with medical care systems which have a plurality of features that are identical to that of Lichtenstein and which provide identical challenges.

(11) Response to Argument

It is argued that none of the applied references provide any hint to the skilled artisan of how to develop the complex computer hardware, software, controls or displays that would be necessary to replace some or all of the conventional electromechanical controls and displays of a conventional hemodialysis system with a functioning touch screen. However, Lichtenstein explicitly discloses that development of complex hardware and software are necessary for controlling and displaying parameters for the disclosed hemodialysis extracorporeal blood treatment system in column 24, lines 30-55 and column 32, lines 26-41. Additionally, Kerns (column 5, lines 50-55) and Rubalcaba (column 6, lines 29-32) address the need for suitable programming and sufficient memory and both throughout teach relatively complex touch screen control systems having a number of subcomponents and functions.

(11) Response to Argument

It is argued that the expressed object in Kerns of preventing confusion of data in the switching and rearrangement of multiple modules are addressed by the teaching of making the modules identical and stackable and does not provide a suggestion for employing a touch screen. However, Kerns also teaches that the touch screen (display 74) is needed to alert the operator of mismatched modules and data and assure that modules and data are correctly matched in column 5, lines 32-59 and column 6, lines 12-20. Additionally, Lichtenstein disclose the problem of correctly arranging multiple modules with matching support structures and sensors (column 6, lines 20-29).

(11) Response to Argument

It is argued that the motivation present in Rubalcaba to prevent user confusion and data entry is highly machine-specific, and that what causes confusion and error with a stack of infusion pump modules are not the same factors as what would cause confusion and error with modules of a medical care system employing a hemodialysis machine such as that of Lichenstein. However, it is submitted that both Lichtenstein (column 6, lines 20-29) and Rubalcaba (column 1, lines 12-19) employ multiple modules, including infusion modules , that may be employed simultaneously and thus have similar, analogous problems with managing the entry and handling of large varying quantities of data used when simultaneous medical procedures are employed.

(11) Response to Argument

The general argument is presented stating in effect that if it were obvious to employ touch screen control systems in combination with extracorporeal blood treatment systems including hemodialysis, such touch screens would have been utilized much earlier than was actually the case. In reply, the examiner asserts that touch screens were one facet of rapidly emerging computer and data processing technology in the late 1980s and early 1990s (the time period of prosecution of the instant application). Initial adaptation of touch screens firstly to relatively simple medical equipment and then to more complex medical equipment, such as extracorporeal blood treatment systems constitutes a natural, obvious progression in the application of relatively new data processing and computer technology. ***See In re Fielder and Underwood 471 f 2d. 640 176 USPQ 300 at page 305 concerning a general contemporary drive toward increasing use of automated data processing techniques being a determining factor in a question of obviousness and***

application of 35 U.S.C. @ 103. Also, Lichtenstein is concerned with use of emerging computer components, generally in column 8, lines 1-16 and column 32, lines 26-41. As acknowledged by all three of the applied references, data processing and computer control facets of medical treatment are quite complex and inherently would be ordinarily expected to require substantial periods of time to be developed within complete medical systems.

Arguments pertaining to objective evidence of secondary considerations of nonobviousness submitted by Appellants to traverse the rejection under 35 U.S.

(11) Response to Argument

It is argued various secondary considerations of non-obviousness including commercial success, industry recognition as attested to by winning of international design awards and copying by competitors of the medical system design embodying the claimed invention (System 1000) is principally due to the development of the touch screen control system. The touch screen control system is stated to be the key feature of the System 1000 and eliminates the very large number of complicated details, and a very large number of conventional discrete controls, knobs and displays that would otherwise be necessary; and by making operation of the entire hemodialysis medical system governed by the touch screen control.

It is submitted, however, that such a touch screen control as present in System 1000 goes far beyond what is actually recited in the instant claims, which only require, at a minimum, the touch screen being operable for changing the setting of a single parameter, out of numerous possible parameters for the many components of the medical system. Nowhere, in the claims is it stated that the touch screen controls the entire operation of the medical system. Importantly, the instant claims do not preclude touch screens employing a combination of touch screen(s) and other data entry and interactive control devices, for instance,

physically separate keyboards, as actually taught in Kerns et al at column 5, lines 56-59. As stated in MPEP 716.03 , the commercial success must be due to claimed features, and not to unclaimed features (See ***Joy Technologies Inc. V. Manbeck, 751 F. Supp. 225, 229, 17 USPQ2D 1257, 1260 (D.D.C. 1990).***

A review of the Declaration and related documents in the file history of the instant application and the parent application (09/067,922) indicates that the design to which commercial success and industry recognition and awards are attributed, emphasizes several features apart from the use of a touch screen. These features included the following:

1) Development of a compact, integral, protective housing for the entire dialysis treatment system including hemodialysis filter, dialysate and extracorporeal blood circulation systems as well as all of the controls;

2) Rounded, smooth, housing surfaces allowing easy cleaning, maintenance and portability;

3) Easy access from the rear of the housing to service parts and components; and

4) Increased safety and reliability embodied in redundant sensors and software features.

The instant claims are completely silent as to claim language concerning housing features or components being integral, particular design or shape of housing or components; servicing or cleaning of components or safety and reliability features. In fact, both teaching references Kerns and Rubalcaba, while employing touch screens, still present relatively complex arrangements of exposed components including cables, tubing, module support and stacking features and other stands and supports for holding fluid supplies and other components. There is no language in the claims specifying the arrangement of components, presence of a housing or any features related to safety, reliability or cleaning features.

Relatedly, it is argued that incorporation of a touch screen reduced operator training time since it could readily incorporate operator prompts and other menu driven indicia for ease of operation and minimal error. However, it is submitted that the instant claims are also silent as to incorporation of operator prompts or menu driven indicia. Further, it is readily appreciated by the ordinarily skilled artisan that such prompts and menu driven indicia are adaptable to any form of computer display or monitor module used with conventional keyboards and do not require use of a touch screen.

(11) Response to Argument

It is extensively argued that development of a touch screen control system for use with hemodialysis medical care systems satisfied a long-felt need in the hemodialysis industry driven by demands of contemporary medical practice and progressive cutbacks in government payback plans. Such long-felt need is stated as evident in the number of research and development efforts undertaken by all entities in the market.

It is submitted that such "long-felt need" can be interpreted as the need to develop a more cost effective and efficient overall hemodialysis medical care system. This "need" has been evident within industry efforts to make improvements with all facets of hemodialysis systems including to materials and mechanical features of the hemodialysis filters to make them more effective at performing dialysis of extracorporeal blood; to develop streamlined cleaning and maintenance procedures and to develop better tubing, connections and support structure.

Specifically regarding length of time elapsed in adapting touch screen control systems medical systems having modular infusion pump components (Kerns and Rubalcaba) to more complex medical systems employing both infusion pump components and hemodialysis components as well as additional components

(Lichtenstein), a comparison of filing or issue dates of the teaching references (1986-1990) with the effective filing date of the instant application (1993) shows a relatively short lapse of time. As emphasized in various text portions of Lichtenstein, computer hardware and software utilized in hemodialysis containing medical equipment is complex and extensive. The ordinarily skilled artisan, deemed to constitute an engineer or scientist with an advanced degree, having both computer science and medical technology expertise, would necessarily require several years of routine research and development to have a reasonable expectation of success in adapting new computer or data processing technology from more simple medical systems to more complex medical systems such as hemodialysis containing system.

(11) Response to Argument

The argument that the commercial success, copying by competitors and industry recognition as attested to by Appellants earning numerous design awards for the company's machine embodying the subject name "System 1000 Dialysis Delivery System" ("System 1000") attests to the non-obviousness of employing the touch screen component is restated. It is submitted that such secondary considerations are not persuasive unless adequate Nexus can be proven between the merits of the claim invention and the evidence offered (***Stratoflex, Inc. v. Aeroquip Corporation (CAFC) 218 USPQ 871).*** In "Stratoflex", despite considerable evidence presented concerning secondary considerations including commercial success and copying by others, the courts decided that such nexus between the evidenced product and the claimed subject matter was not adequately shown for the secondary considerations to be persuasive.

After full consideration and review of the Declaration and related documents in the file history of the instant application and the parent application (09/067,922), it is submitted that the required nexus between the claimed subject matter and the evidence of commercial success is not shown. The recognition, copying

and success of System 1000 is deemed to be in large part a result of many factors other than the touch screen control including the following:

1) development of a compact, integral, protective housing for the entire dialysis treatment system and controls (Note that there is no suggestion for such housing in Rubalcaba or Kerns despite inclusion of touch screen controls);

2) rounded, smooth housing surfaces allowing easy cleaning;

3) easy access from the rear of the housing to service parts and components; and

4) increased safety and reliability including many redundant sensors and software feature; and

5) adaptation of the touch screen for control of generally all operating parameters of the entire hemodialysis medical care system

The instant claims are completely silent concerning each of these features of System 1000.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Joseph Drodge

Joseph Drodge

Primary Examiner

Group 1723

Conferees

Joseph Drodge Joseph Drodge

Wanda Walker Wanda L Walker, SPE AU 1723

Michael Ball

Joseph Drodge
JOSEPH W. DRODGE
PRIMARY EXAMINER

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Designation of Panel

Pursuant to 35 U.S.C. § 6(b) , it is **ORDERED** that the panel of the Board of Patent Appeals and Interferences (BPAI) designated to decide this case shall consist of the following Administrative Patent Judges (APJs):

1. Judge Warren
2. Judge Krass
3. Judge Pak

~~Non-OB~~
☒ Heard **Hrg date:** 7-15-03
☐ Redesignation
☐ Expanded Panel

Examiner Requests to Attend Hearing: ☐ Yes ☐ No

CIRCLE ONE: MIX BIO CHEM ELEC

Bruce H. Stoner, Jr.
Chief Administrative Patent Judge

Rev. 08/01